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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,425	09/07/2004	Achim Weber	P/ 2107-253	9293
2352 7590 06/11/2007 OSTROLENK FABER GERB & SOFFEN 1180 AVENUE OF THE AMERICAS NEW YORK, NY 100368403			EXAMINER YU, MELANIE J	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/500,425	Applicant(s) WEBER ET AL.	
	Examiner Melanie Yu	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65, 78, 80, 82, 84, 86, 88, 90, 92-96 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-9, 13-22, 24-26, 29-31, 35-46 and 90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/20, 1/26, 6/28</u> | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 5,10-12,23,27,28,32-34,47-65,78,80,82,84,86,88 and 92-96.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I, claims 1-46, in the reply filed on 27 March 2007 is acknowledged. Applicant provides no arguments as to why the restriction requirement is improper. Claims 5, 10-12, 23, 27-28, 32-34, 47-65, 78, 80, 82, 84, 86, 88 and 92-96 have been withdrawn as being drawn to a non-elected invention. Claim 90 has been rejoined with group I.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 3, 7, 15 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 3, the term "and/or" is unclear because it is vague as to whether both the carrier and the surface must be made of the recited materials or whether just one is required to be made from the recited materials.

Claim 7 recites that a layer of a bonding agent is arranged between the carrier surface and the micro carrier, and it is unclear whether the bonding agent of claim 7 is the same as the bonding agent of claim 1. It is vague as to whether claim 7 further limits claim 1 or merely recites limitations that were previously recited in the independent claim 1 from which claim 7 depends.

Claim 15 recites the term "and/or" and it is unclear how a biologically active molecule can be bound both covalently and non-covalently.

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With respect to claim 36, it is unclear what is meant by further molecules bound to the bound molecules. It is unclear whether additional molecules are bound to the bound molecules or whether the molecule specific molecules around bound to the bound molecules. Furthermore, the phrase "the bound molecules" lacks antecedent basis in the claims and it is unclear whether "the bound molecules" are the biologically functioning or active molecules.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-4, 6, 7, 13-17, 19-22, 24-26, 29-31, 35-46 and 90 are rejected under 35 U.S.C. 102(e) as being anticipated by Mirkin et al. (US 2002/0127574).

Mirkin et al. teach an element comprising a carrier with a surface (transparent substrate, Fig. 13B) and at least one microstructure on the carrier surface (single microstructure shown, Fig. 13B, bottom two figures), wherein the microstructure consists of individual components in the form of nanoparticles (circular elements are gold nanoparticles, Fig. 13B), which have molecule specific detection sites with one or more first functional groups (DNA absorbed onto particles, Fig. 13B) to which biologically functioning or active molecules bind to the first functional groups can be bound in a directional manner and thus make possible the addressability of the microstructure (analyte DNA strand hybridized to first functional group, Fig. 13B), and wherein between the surface of the

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carrier and the microstructure at least one layer of a bonding agent that is a self assembled monolayer based on thiol is provided to ensure permanent adherence of the nanoparticles (nanoparticles bonded to the surface through thiol monolayer, Fig. 13B).

Regarding claims 2-4, Mirkin et al. teach the microstructure having a diameter of 375 μm on the planar, glass slides (surface is a glass slide, which is planar, par. 133; diameter of spot a length parameter and is within the recited range of 10 nm to 999 μm , par. 383).

With respect to claim 6, Mirkin et al. teach the surface of the carrier having a layer of a chemical compound that prevents nonspecific attachment of biological molecules to the carrier surface (par. 372).

Regarding claim 7, Mirkin et al. teach a layer of a bonding agent arranged between the carrier surface and the microstructure (nanoparticles bonded to the surface through thiol monolayer, Fig. 13B).

With respect to claims 13-15, Mirkin et al. teach the nanoparticles comprise a core and a surface that has the molecule specific recognition sites covalently bound to the nanoparticles (oligonucleotides with a functional group that binds to the nanoparticles is bound to the nanoparticles, par. 61) and biologically active molecules bound to the molecule-specific recognition sites (oligonucleotides that are recognition oligonucleotides are attached to the biologically active molecules on the nanoparticles, par. 62).

Regarding claims 16 and 17, Mirkin et al. teach that the molecules are bound while preserving their biological activity (par. 7 and 62) and the bound molecules are nucleic acids (par. 7).

With respect to claims 19 and 20, Mirkin et al. teach the molecule specific recognition sites comprising one or more first functional groups and the bound molecules

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comprise complementary second functional groups that bind the first functional groups (par. 173) and the function group being an amino or aldehyde (par. 180).

Regarding claims 21 and 41-46 are drawn to methods of making the functional element and does not provide additional structural limitations. Mirkin et al. teach the limitations recited in claim 1 and therefore has the same structure as a functional element produced by the methods recited in claims 21 and 41-46.

With respect to claims 22, 24-26 and 29, Mirkin et al. teach the first functional groups bound to the surface of the nanoparticles via a spacer (par. 242) and the core of the nanoparticles being polystyrene (par. 180) and having a diameter of 5-150 nm (par. 107), which falls within the recited range of 5 to 500 nm.

Regarding claims 30, 31 and 35, Mirkin et al. teach the core or the bound molecule having an anchored fluorescence marker (oligonucleotide or nanoparticles labeled with fluorescent marker, par. 178).

With respect to claims 36-38, Mirkin et al. teach further molecules bound to the bound molecules (par. 323) and the microstructure consisting of a single (par. 104) or several nanoparticles layers (par. 83).

Regarding claims 39 and 40, Mirkin et al. teach that within several microstructures, the nanoparticles making up the microstructures have different molecule specific recognition sites that are arranged on the carrier surface and various molecules are bound to the microstructures (different nucleic acids, par. 173).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having

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ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mirkin et al. (US 2002/0127574) in view of Montgomery et al. (US 6,093,302).

Mirkin et al. teach the bonding agent being a self assembled monolayer based on thiol, but fail to teach the bonding agent being a polymer with chemically reactive groups.

Montgomery et al. teach using a bonding agent being a thiol or a hydrogel polymer to attach molecules to a substrate (col. 19, line 64-col. 20, line 16), in order to provide direct attachment of molecules to a substrate through a material that overlays the substrate.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the functional element of Mirkin et al., a hydrogel layer to attach the nanoparticles to the substrate as taught by Montgomery et al. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent attachment technique and since only the attachment material would have been altered and the same attachment technique would be obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

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5. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mirkin et al. (US 2002/0127574) in view of Mirkin et al. (US 2002/0132371).

Mirkin et al. ('574) teach the biologically active molecules are nucleic acids, but fail to teach them being antibodies.

Mirkin et al. ('371) teach that nucleic acids, antibodies and other specific protein binding proteins (col. 175) may be used in a similar device to provide for detection or protein analytes.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the function element of Mirkin et al. ('574), proteins instead of nucleic acids as taught by Mirkin et al. ('371), depending on whether detection of a protein analyte is detected.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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